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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,890

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04/03/2009

EXAMINER

MACAULEY, SHERIDAN R

ART UNIT

PAPER NUMBER

1651

NOTIFICATION DATE

DELIVERY MODE

04/03/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No. 10/595,890	Applicant(s) COURTOIS ET AL.	
	Examiner SHERIDAN R. MACAULEY	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A response and amendment were received and entered on November 14, 2008 and January 7, 2009. All evidence and arguments have been fully considered. Claims 1-4 and 6-11 are pending and examined on the merits in this office action.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 14, 2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4 and 6-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The claims are rendered indefinite by the term "lifts up only between 5 and 50% of the length of the culture chamber" in claims 1, 8 and 9. It is unclear whether applicant intends for the term to mean. For instance, the term could mean that the lifting part of

the plate is situated such that 5 to 50% of the culture chamber is lifted (i.e., the remaining 50 to 95% is not lifted) or whether the distance that the mechanism lifts (e.g., vertically) is the equivalent to 5 to 50% of the length of the culture chamber.

5. Claim 2 is rendered indefinite by the term "lifts up from 8 to 20% of the surface area of the lower part of the culture chamber" for similar reasons as set forth for claim 1.

6. The claims are also rendered indefinite by the recitation of "a wave induction mechanism comprising a plate that lifts" in claims 1, 8 and 9. It is unclear whether applicant intends for the wave induction mechanism or the plate to perform the specified lifting act.

7. Claim 2 recites the limitation "wave induction system". There is insufficient antecedent basis for this limitation in the claim. The claim depends from claim 1, which recites "wave induction mechanism". It is unclear whether the claim refers to the movement of the entire system, the mechanism, or the plate recited in claim 1.

8. Claims 3 and 10 are rendered indefinite by the terms "to an angle of 1 to 90 degrees" and "to an angle of 1 to 25 degrees," respectively. It is unclear what this angle is relative to. For instance, the angle could be relative to the horizontal, to the position of the chamber, or to the position of the wave induction mechanism.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-4 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbard (US 2005/0063250 A1; document cited in prior action) in view of Singh (US 6,190,913; document cited in prior action). Claim 1 recites a cell culture apparatus comprising a flexible culture chamber, and a wave induction mechanism comprising a plate that lifts up only between 5 and 50% of the length of the culture chamber and is compatible with large scale-up of a culture medium in an amount up to 1000 liters.

Claim 2 recites the cell culture apparatus according to claim 1, wherein the wave induction system lifts up from 8 to 20% of the surface area of the lower part of the culture chamber. Claim 3 recites the cell culture apparatus according to claim 1, wherein the wave induction mechanism lifts up part of the lower part of the culture chamber to an angle of 1 to 90 degrees. Claim 4 recites the cell culture apparatus according to claim 1, wherein the culture chamber comprises means to circulate air. Claim 6 recites the cell culture apparatus according to claim 1, wherein the culture chamber is a flexible plastic bag. Claim 7 recites the cell culture apparatus according to claim 1, wherein the culture chamber is filled from 10 to 80%. Claim 8 recites a method for cultivating plant cells, animal cells, or microorganisms, the method comprising providing a cell culture apparatus that comprises a flexible culture chamber, and a wave induction mechanism comprising a plate that lifts up between 5 and 50% of the length of the culture chamber and is compatible with large scale-up of a culture medium in an amount up to 1000 L; and cultivating plant cells, animal cells, or microorganisms in the cell culture apparatus. Claim 9 recites a method for producing biomass cells, embryogenic plant cells, metabolites, secondary plant metabolites and/or recombinant molecules comprising providing a cell culture apparatus that comprises a flexible culture chamber, and a wave induction mechanism that lifts up between 5 and 50% of the length of the culture chamber and is compatible with large scale-up; and growing biomass cells, embryogenic plant cells, metabolites, secondary plant metabolites and/or recombinant molecules in the cell culture apparatus. Claim 10 recites the cell culture apparatus according to claim 1 wherein the wave induction mechanism lifts up part of

the lower part of the culture chamber to an angle of 1 to 25 degrees. Claim 11 recites the cell culture apparatus according to claim 1 wherein the culture chamber is filled from 20 to 40%.

13. Hubbard teaches a cell culture apparatus comprising a flexible culture chamber (i.e. a fermentor) and a wave induction mechanism (a bag that is capable of being selectively pressurized and deflated; abstract). Hubbard teaches that the wave induction mechanism may comprise a plate (p. 2, par. 38). Hubbard teaches that the wave induction mechanism may be located under a portion of the bag, and lifts between 5 and 50% of the bag shown in fig. 4 (p. 2, par. 34, fig. 4, p. 3, par. 51; note that from 8 to 20% of the bag may also be lifted in the apparatus as depicted by fig. 4). The bag shown in fig. 4 is lifted at an angle of between 1 and 90 degrees. Hubbard teaches that the culture chamber may be a flexible plastic bag and that the culture chamber comprises a means to circulate air (p. 2, par. 30, p. 3, par. 45). Hubbard teaches that the bags may be filled from 20 to 80% of the bag volume (p. 2, par. 29). Hubbard teaches that the apparatus may be used in a method for producing biomass cells, such as microorganisms (p. 2, par. 29). The reference does not specifically teach that the plate of the wave induction mechanism lifts the bag and does not teach the specific angles to which the chamber is lifted that are recited in the claims.

14. Singh teaches a cell culture apparatus comprising a flexible cell culture chamber (such as a plastic bag) and a wave induction mechanism (abstract, fig. 1). Singh teaches that the wave induction mechanism comprises a plate that has a pivot point which alternately rocks each side of the cell culture chamber (col. 4, lines 7-17, fig. 1).

Singh teaches that the wave induction mechanism moves the cell culture chamber between one and fifteen degrees (col. 4, lines 18-21).

15. At the time of the invention, a cell culture apparatus comprising nearly all of the claimed components was known, as taught by Hubbard. It was further known that similar cell culture apparatus could comprise a plate that lifts the culture chamber, as taught by Hubbard. One of ordinary skill in the art would have been motivated to combine these teachings to modify the apparatus of Hubbard to use a plate that lifts the culture chamber because Singh teaches that a variety of lifting devices for lifting the culture chamber may be used in a similar cell culture apparatus (col. 4, lines 10-17). One would thus have recognized that one wave induction mechanism could have been replaced by another in a similar apparatus with a reasonable expectation of success and that the inflatable bag of Hubbard could have been replaced by a lifting platform, such as those taught by Singh. One of ordinary skill in the art would further have had a reasonable expectation of success in using a plate to lift the culture chamber in the mechanism of Hubbard because Hubbard teaches that such a plate is compatible with the system and Singh teaches that lifting platforms may be used with flexible culture chambers. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings cited above to arrive at the claimed invention.

16. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

17. Applicant's arguments filed November 14, 2008 have been fully considered but they are not persuasive. Applicant argues that the claims are sufficiently definite.

Applicant argues that the cited references do not teach all aspects of the claimed invention, specifically that the references do not teach an apparatus that is compatible with large scale-up. Applicant argues that the teachings of the cited references do not provide the same advantages as the invention recited in the instant claims.

18. In response to applicant's argument that the claims are sufficiently definite, it is noted that, although applicant has amended to the claims in an effort to clarify the claimed invention, the claims are indefinite for the reasons set forth in the rejections above. Specifically, although applicant argues that the claims are clear in that a portion of the culture chamber is lifted by the wave induction mechanism, it is noted that the claims are unclear because they have an alternate interpretation. Applicant is advised that they may amend the claims to recite that the mechanism "lifts up only a portion of the culture chamber, wherein said portion is between 5 and 50% of the length of the culture chamber," or some other term that is sufficiently definite.

19. Regarding applicant's argument that the cited references do not teach all aspects of the claimed invention, specifically that the references do not teach an apparatus that is compatible with large scale-up, it is noted that the references teach cell culture systems that may be used with large volumes, such as with 500 liters as taught by Singh. Although applicant argues that the term "compatible with a large scale-up of a culture medium in an amount up to 1000 liters" distinguishes the invention over the prior

art, it is noted that any culture volume of up to 1000 liters meets the limitations of this language. If applicant intends to distinguish their invention over the prior art on the basis of the ability to operate with a culture medium of 1000 liters, applicant is advised to amend the claims to recite this limitation, such as with the term "wherein the apparatus is compatible with volumes of 1000 liters." However, there is no teaching in the prior art that indicates that the apparatus of the prior art are not compatible with these large volumes. As applicant notes, the apparatus of Singh is compatible with volumes of 500 liters and a two-fold increase in volume would likely be a matter of routine experimentation to one of ordinary skill in the art.

20. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the advantages cited by applicant, such as the improved mixing/aeration mechanism and the ability for the apparatus to be placed on a floor surface) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus, applicant's argument that the references do not teach the claimed features is not persuasive.

21. Therefore, applicant's arguments have been fully considered, but they are not found to be persuasive.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A. Davis/
Primary Examiner, Art Unit 1651